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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Anne Dollard
CHIRON CORPORATION
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,066

Applicant(s)

THUDIUM ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This office action is in response to an amendment and response to restriction requirement filed 4/8/03 as paper No. 9. Claims 1-31 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 9 is acknowledged. Claims 23-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Drawings

Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

Specification

The disclosure is objected to because of the following informalities: A copy of the sequence listing was sent with the amendment filed 4/8/03, Paper No. 9. Therefore, there are two copies of the sequence listing in the specification. Please cancel one sequence listing by amendment.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 15, line 30. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1- 2, 5-6, 9, 12-15, 17, and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Chapman et al. (NAR Vol 19, No 14, 3979-3986, applicant cited).

Chapman et al. teach the generation of an expression construct, which comprises the human cytomegalovirus (hCMV) promoter/enhancer region as well as intron A. The nucleotides inclusive of 1-25 or 1-51 as well as 741-820 or 775-820 are included in the vector. The intron shown in figure 3D lacks the full-length sequence of hCMV intron A as it contains a mutation in the NF1 binding site. It is shown that a vector containing this fragment expresses 2X the level of FVIIgp92 as one without intron A (table II versus table III). COS7 host cells containing these constructs are provided (page 3980, column 1 last paragraph).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and by dependency claims 14-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-13 are unclear for reciting, "the expression construct achieves expression levels". Specific coding sequences within the expression construct can be expressed but not the expression construct itself. As recited, it is unclear what is expressed, as there are no cited coding sequences in operative linkage with the recited Intron A sequence. Also it is unclear to what measured refers, protein or RNA.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of hCMV Intron A fragments comprised sequences having at least 75% sequence identity to contiguous sequences found at positions 1-25 or 1-51 and 775-820 or 741-820 of SEQ ID 1 that can drive expression levels to two-fold, ten-fold or fifty-fold compared to a control without intron A.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed

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correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. The invention claims as an essential element that the intron A fragment drive expression levels to two-fold, ten-fold or fifty-fold that of a control construct without the intron A fragment. It is disclosed that a construct containing an intron A fragment from 1-51 and 741-834 increases expression by two-fold over a 'parent' vector in *in vitro* assays (figure 5) and less than two-fold in *in vivo* assays (figure 7). However, there is no actual reduction to practice or clear depiction of what structures or properties are required for generation of a intron A fragment or a fragment with 75% identity to the sequences found at positions 1-25 or 1-51 and 775-820 or 741-820 of SEQ ID 1 that can drive expression levels to two-fold, ten-fold or fifty-fold compared to a control without intron A. Neither the instant disclosure nor the prior art provide a correlation between the structures of the recited intron A fragments and their ability to drive expression. Given the diversity of fragments encompassed by the rejected claims and the inability to determine which fragments will also have the essential element of driving expression two-fold, ten-fold or fifty-fold, it is concluded that the skilled artisan would not be able to reliably envision those other embodiments capable of satisfying the functional limitations of the claims. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucell, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kay Pinkney, patent analyst, whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

June 13, 2003

Gerald G. Lotters Jr.
PATENT EXAMINER
Gerald G. Lotters Jr.
A.U. 1636